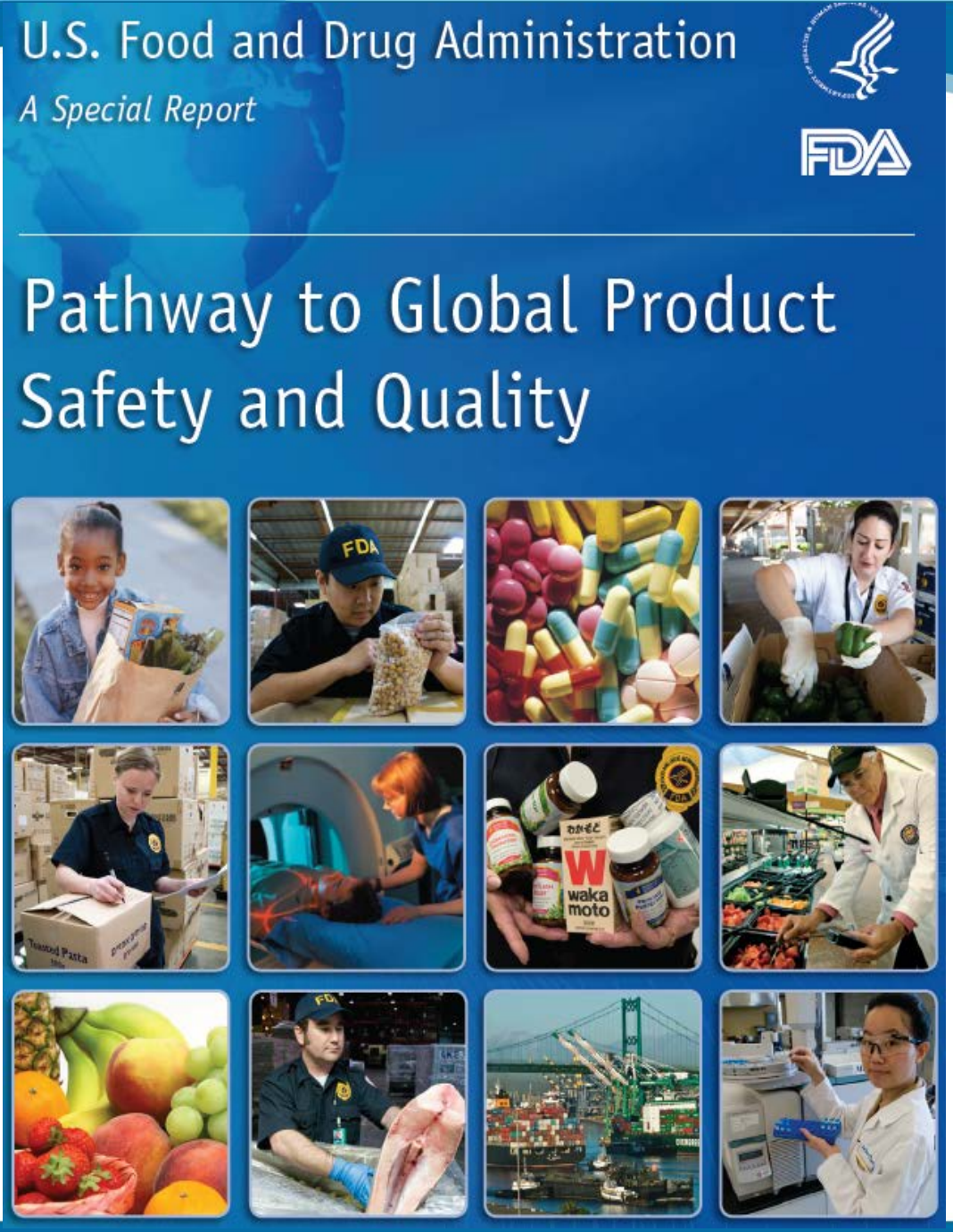
FDA IT and Informatics Transformation

FDA Science Board

May 2, 2012

Eric D. Perakslis Ph.D.

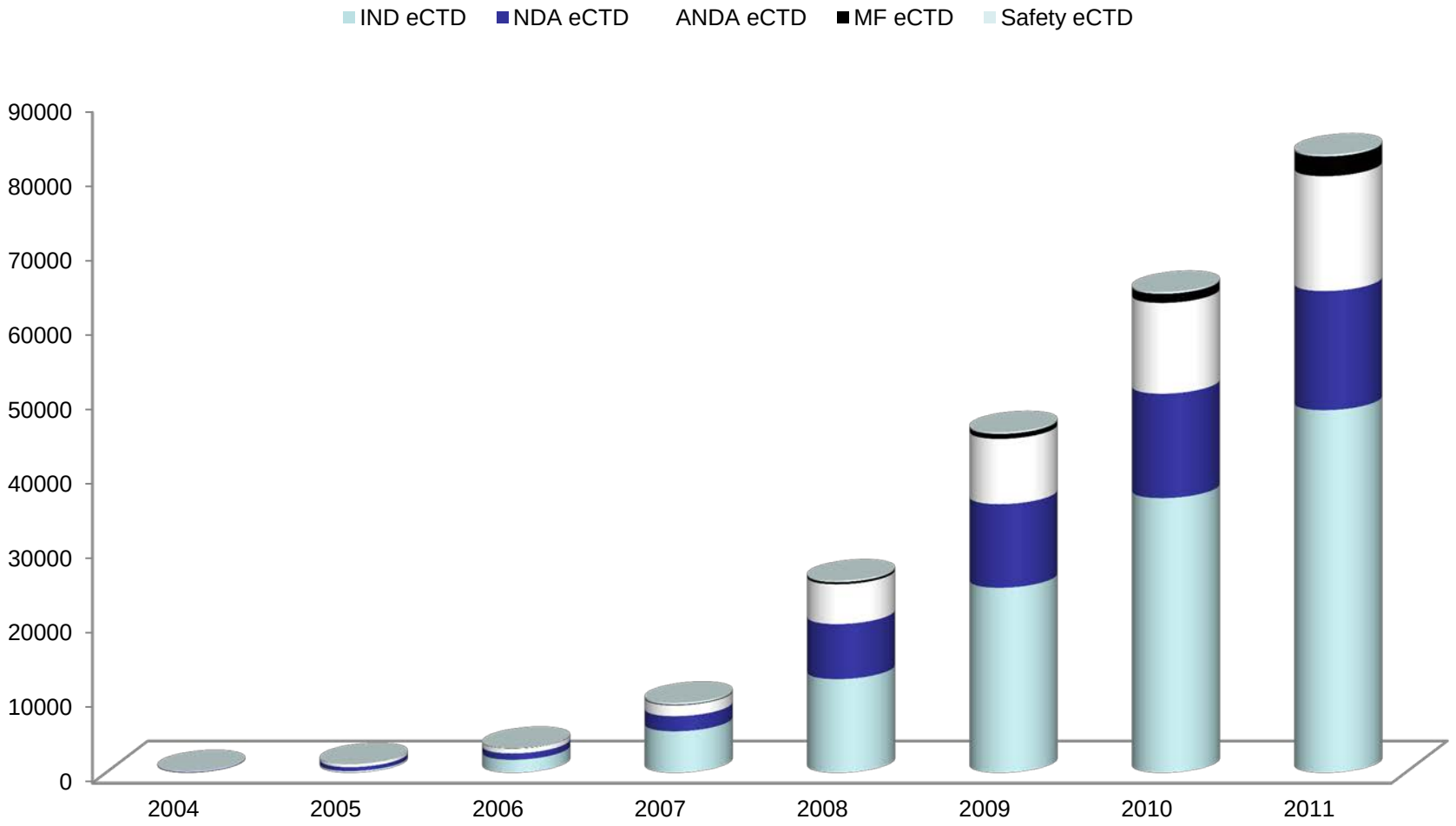
and many others!



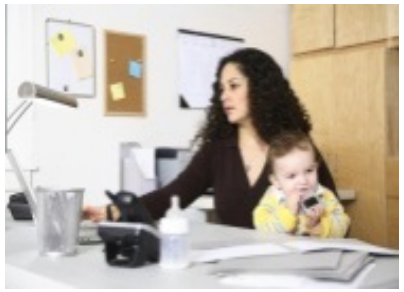
- Themes:
  - Globalization and Partnerships
    - Prevention-Based Controls
    - Supply Chain Accountability
  - Business Process Improvements
  - Food Safety Modernization Act

eCTD Submissions by Application Type

FY2004 through FY2011



What does GREAT look like?
For most…it is home.



- Reliable, predictable, fast and available
- Infrastructure on demand
- Applications that eliminate barriers to productivity
- The applications evolve at 10-15% new functionality per year
- 5-year capital life cycle – implies development in less than 18 months…
- Compelling annual narrative that drives investment and confidence

Move away from monolithic Enterprise Systems and towards Reusable Components

Enterprise System

- Requirements paralysis due to number of stakeholders and specific requirements
- Large, costly and long running projects with little benefit for users early on
- Not able to take advantage of new/emerging technology once committed
- Difficult to make course corrections once effort is underway

Reusable Components

- Use off-the-shelf components or components built by FDA
- Focus on both similarities and differences vs one size fits all
- Decrease unnecessary reinvention of technology
- Require building only the parts that are application specific
- More flexibility to change course based on lessons learned

Service-based Architecture and Capability Roadmap Example: Mobility and Virtualization

Drivers include: our increasingly remote workforce, mobility-only capability needs, cost and efficacy and the superior software development and deployment capabilities

Required Services

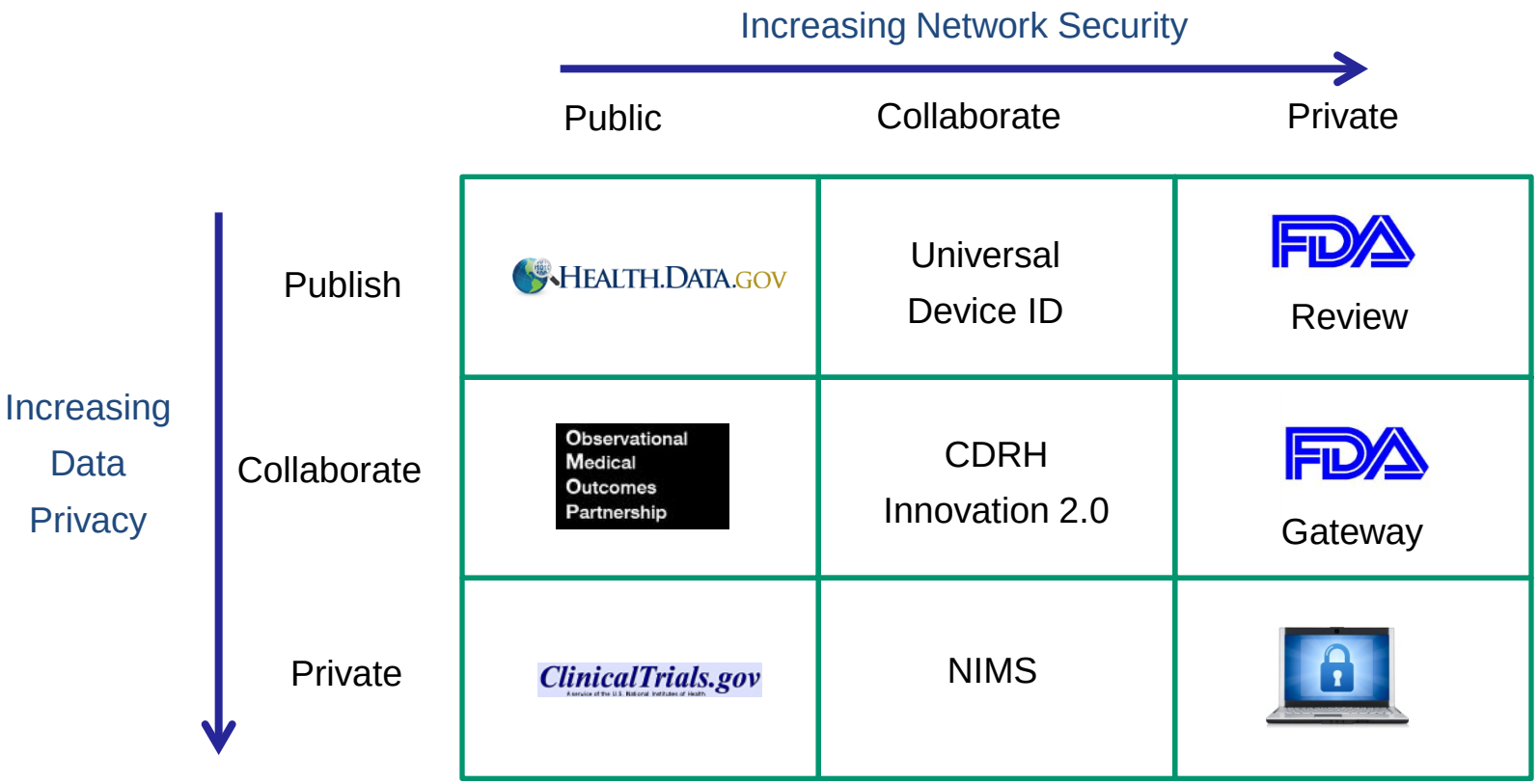
- email
- document mgt
- tele-presence
- a App access
- network connectivity
- eSignature
- eMeetings
- document delivery
- eSurveillance
- ePix and Video
- eCRM
- … …

Each service corresponds to 1-3 solution components

Menu

Each center assembles Components for their own solution

*FDA Model - Building Healthcare On the Grid: A Comprehensive Strategy for Data Security and Network Design



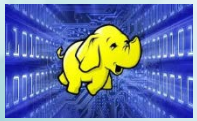
*Approved for design and implementation planning on 2/29 by the HHS Domain IT Steering Committee

FDA's Move to the Cloud

Private Cloud

- Modernized Data Center
- 89.1 % Virtualized
- Increased Reliability 98.3% to 99.9996%

Next-Generation Sequencing



Scientific Computing

Big Data and Hadoop

Disaster Recovery

Public Cloud

- Piloting SaaS and IaaS
- Security Assessments underway
- Economic Assessments
- Discover new approaches to the use of health data
- Unleashing FDA's releasable Data Sets

J2EE Application Cloud (40-1)

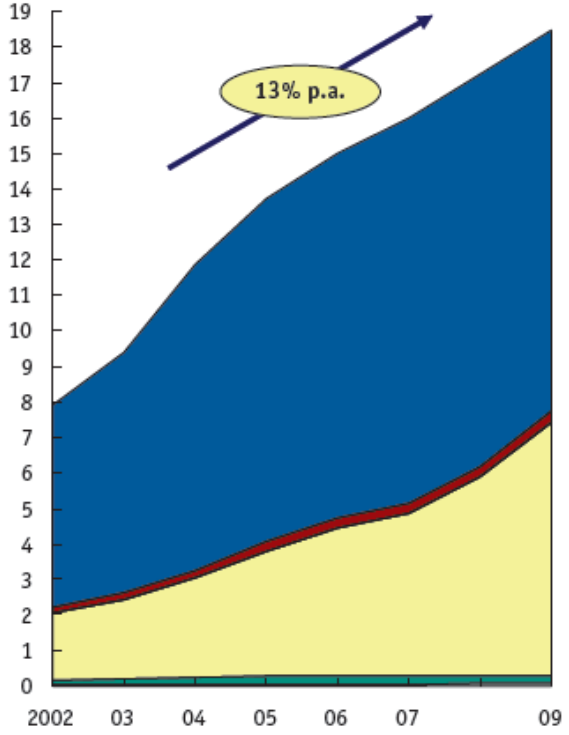
DB Cloud 110 to 18 DB Servers

High Performance Computing

Import shipments of FDA-regulated products have been growing at 13 percent per year.

Imported lines[1] (millions)

Total = 7.9 MM in 2002; total = 18.5 MM in 2009



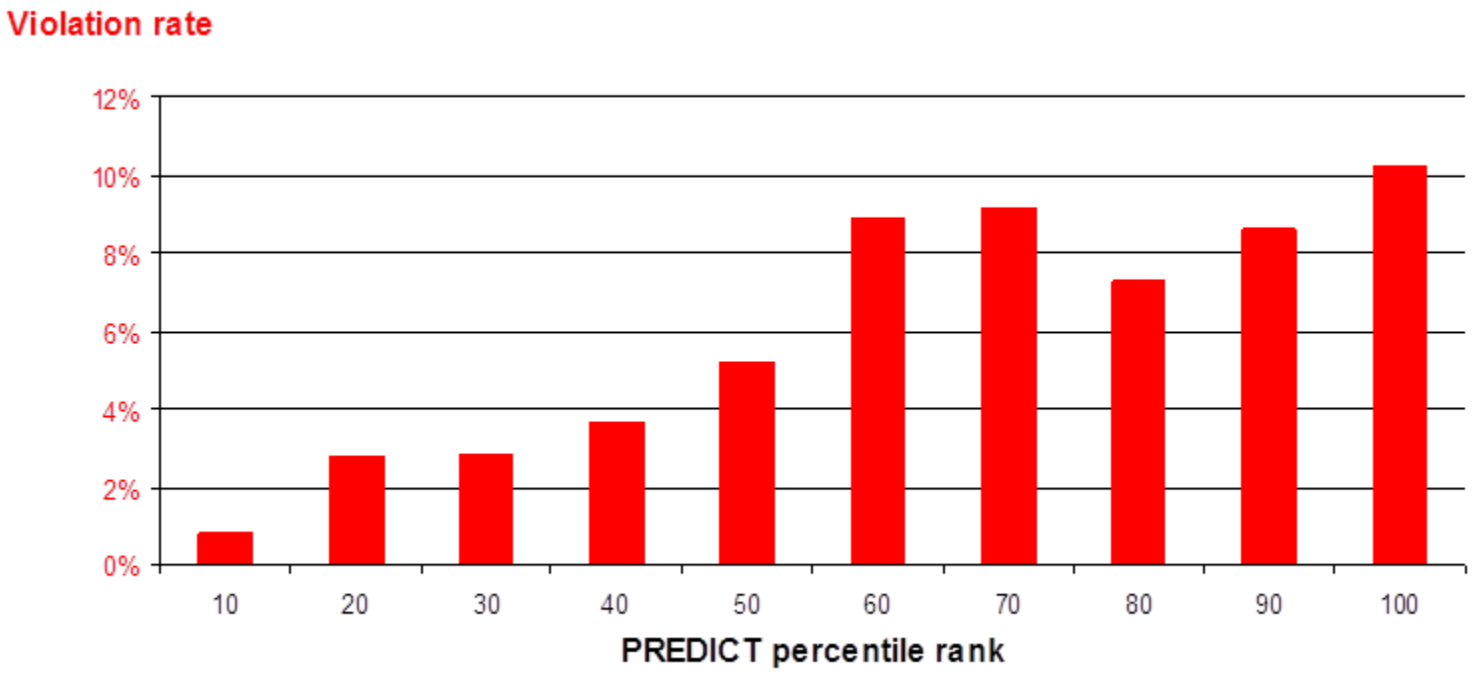
	CAGR 2002-09	Explanation of center's products
Foods	9.5%	• Food products for human, animal, pet use, except meat and poultry • Articles for cleansing, beautifying, promoting attractiveness of body
Drugs	12.9%	• Prescription and OTC drugs for human
Devices	20.8%	• Medical devices for human use • Products that emit radiation (e.g., microwaves, lasers, x-ray machines)
Veterinary products	6.7%	• Drugs, devices, and food additives for animals and pets
Biologics	15.8%	• Blood products, vaccines, and tissues for transplantation

1 An import line represents the portion of a shipment listed as a separate item on an entry document. The number of units can vary.

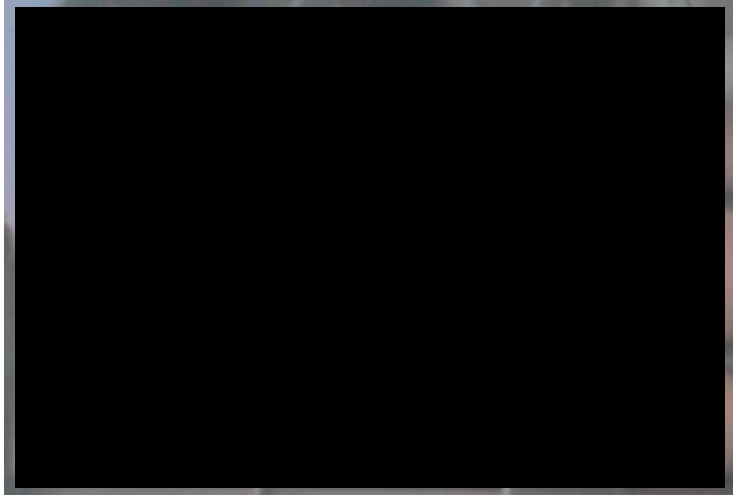
Source: FDA

Globalization and Partnerships

PREDICT Helps Target Our Resources Based on Risk…



Path to Mobility for Food Safety



- Modernize FDA's Inspection Program starting with Eggs
- Intelligent Questionnaire (IQ).
  - Prototyped and field tested 2011
  - Rolling out full pilot in 2012
- Findings: 59% reduction in time spent performing inspection & producing inspection reports.

Center for Tobacco Products (CTP)

Office of Compliance and Enforcement's State Inspection Program

Inspections of Tobacco Retailers

Customized web application: FDA's Tobacco Inspection Management System (TIMS)

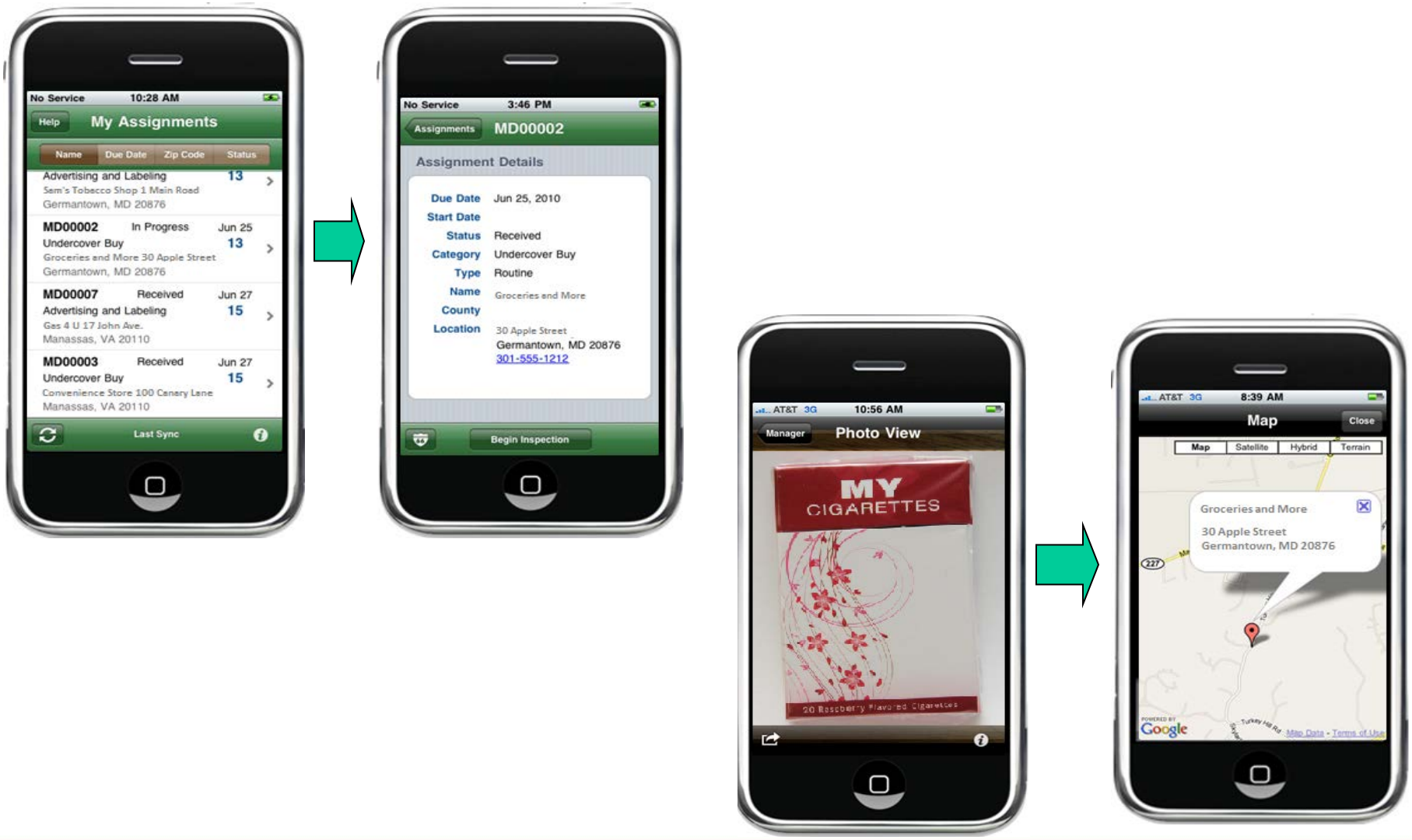
- Holds the inventory of tobacco retail establishments as provided by states
- Allows for creation and tracking of inspectional assignments
- Stores results of inspections, including photographic evidence

Mobile Devices (iPhones/iPads)

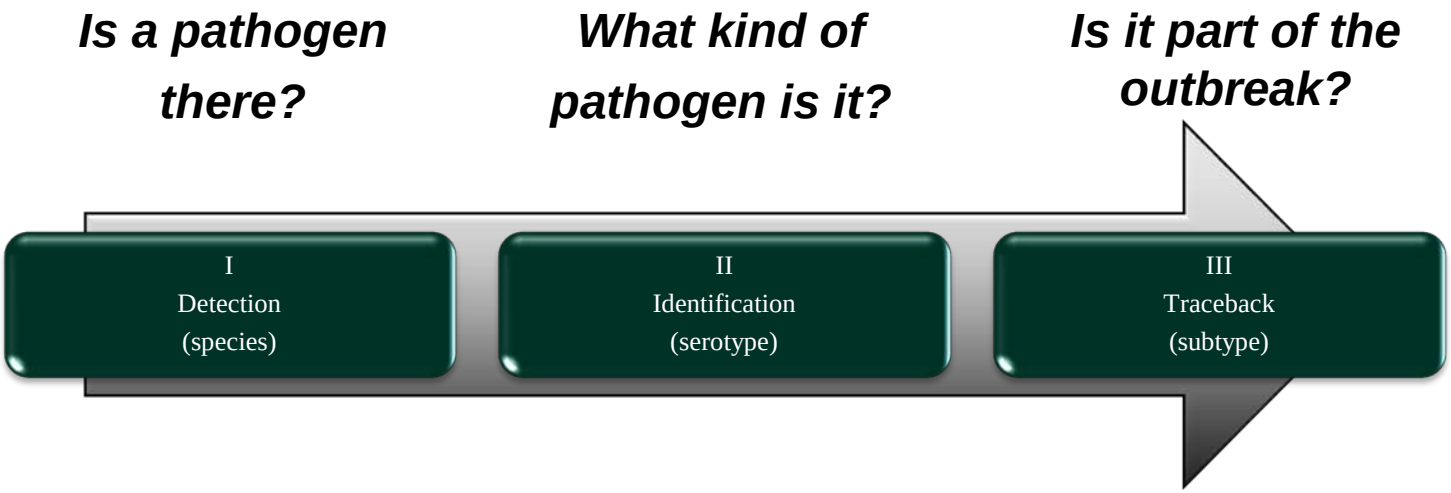
- Provides an interface for inspectors to efficiently conduct checks at retail sites
- Built-in camera captures photographic evidence
- Customized mobile application captures inspection results
- Work offline anywhere in the country and then remotely sync with TIMS
- Map capability to locate retailers
- Portable and secure

**To date, states have completed more than 50,000 inspections of tobacco product retailers*

CTP iPhones


No Service 10:28 AM
Help
My Assignments
Name
Due Date
Zip Code
Status
Advertising and Labeling
Sem's Tobacco Shop 1 Main Road
Germantown, MD 20876
13
MD00002 In Progress Jun 25
Undercover Buy
Groceries and More 30 Apple Street
Germantown, MD 20876
13
MD00007 Received Jun 27
Advertising and Labeling
Gas 4 U 17 John Ave.
Manassas, VA 20110
15
MD00003 Received Jun 27
Undercover Buy
Convenience Store 100 Canary Lane
Manassas, VA 20110
15
Last Sync
No Service 3:46 PM
Assignments
MD00002
Assignment Details
Due Date Jun 25, 2010
Start Date
Status Received
Category Undercover Buy
Type Routine
Name Groceries and More
County
Location 30 Apple Street
Germantown, MD 20876
301-555-1212
Begin Inspection
AT&T 3G 10:56 AM
Manager
Photo View
MY
CIGARETTES
AT&T 3G 8:39 AM
Map
Close
Map
Satellite
Hybrid
Terrain
Groceries and More
30 Apple Street
Germantown, MD 20876
227
Google

Outbreak investigations are a 3-step process:



Next-Generation sequencing can be used to address different facets of outbreak response:

- Have we seen this isolate before? (Compare to reference isolates)
  - Do these clinical isolates form a cluster (i.e. are is it outbreak or background)?

  (Compare to reference and other outbreak isolates)
  - Is there a link between food/environmental and clinical isolates?

  (Compare to reference, clinical, and food/environmental isolates)

CDER IT Initiatives

Application Standardization & Modernization

- Implementing a SAS Drug Development solution to automate the validation and loading of incoming CDSIC SDTM datasets, to notify review staff, and to allow access to the study data via COTS analysis tools.
- Working with ICH partners on next generation of Electronic Common Technical Document (eCTD) – Based on the Health Level Seven (HL7) Regulated Product Submission (RPS).
- Planning for transition to electronic submissions required under PDUFA V

Drug Safety

- Implementing next generation of post market safety surveillance system combining a COTS product with a business intelligence solution

Pharmaceutical Product Quality Platform

- Planning for development of a Pharmaceutical Quality Platform including a product and facilities master database with an integrated inspection management capability for facilities and sites

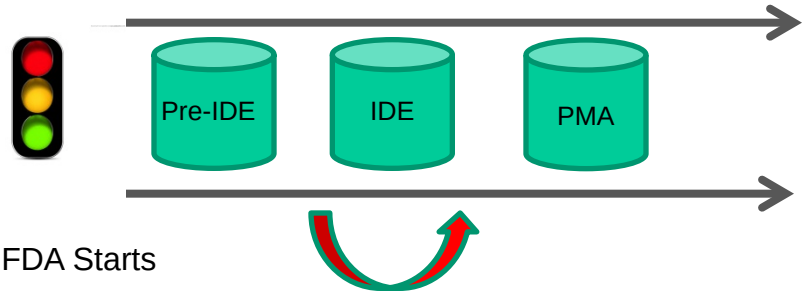
CDRH Innovation Pathway 2.0

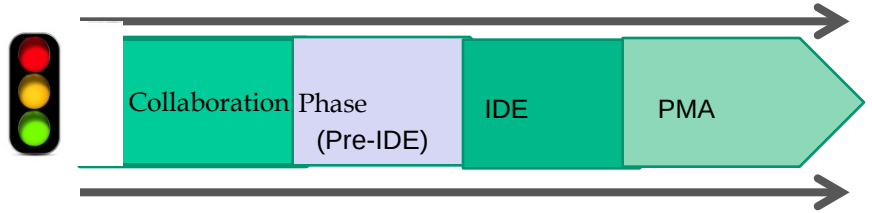
About half a million Americans suffer from end-stage kidney disease and there has been no major innovations in the last 20 years for devices f treatment

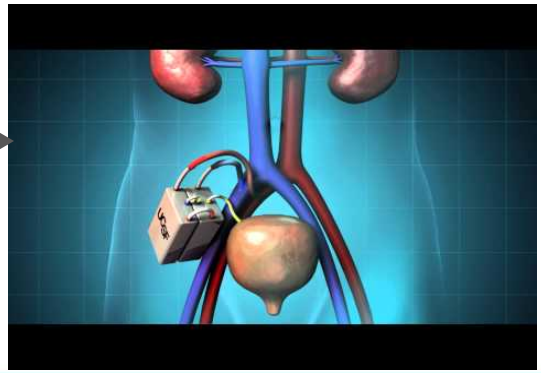
Current Problem: Multiple Challenges Face FDA in Trying to Facilitate a Culture of Innovation: Poor User Experience, Silos, Lengthy Timelines.

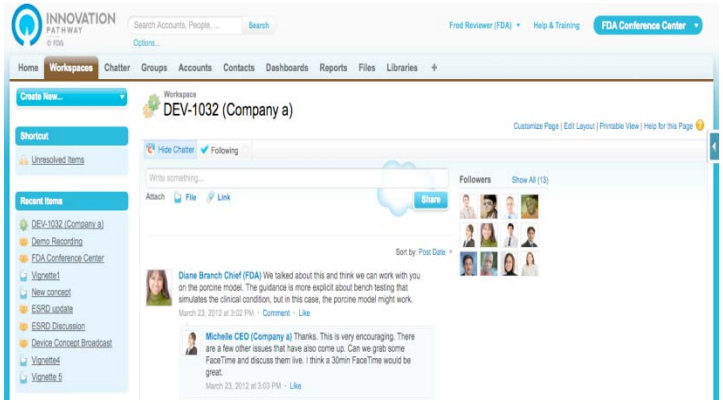
Hypothesis: Early collaboration will break down barriers and bring novel innovative devices to the patient faster.

Pilot: Establish collaboration at the innovation phase of the novel medical device idea.



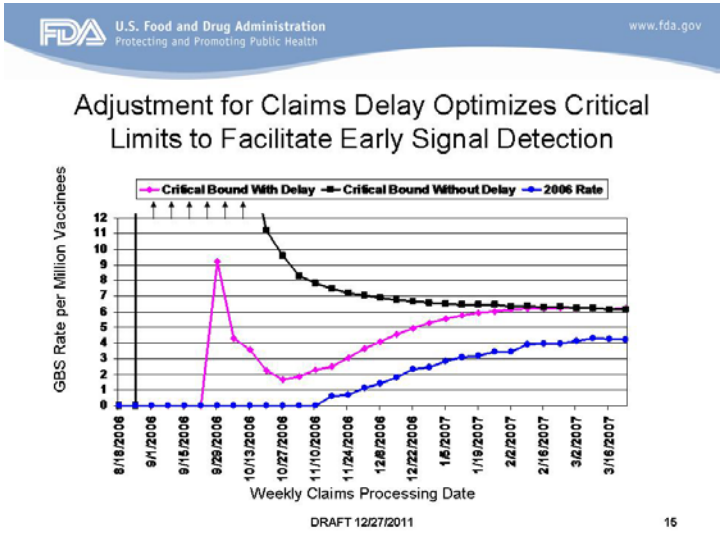






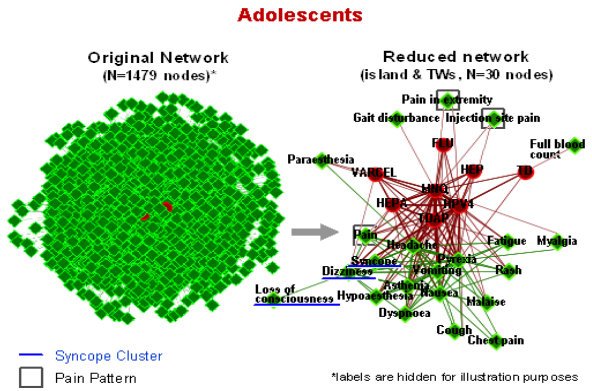
Rapid Assessment of Vaccine Safety

- Developed a novel approach to near real-time safety surveillance adjusting for delay in claims in collaboration with CMS



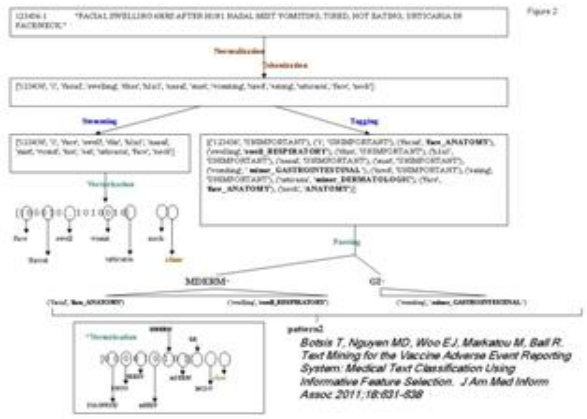
- 2009–2010 season: monitored safety of seasonal and H1N1 pandemic influenza vaccines
  - Approximately 45 million CMS beneficiaries and more than 3 million H1N1 pandemic vaccinations monitored
- Monitoring of GBS after seasonal influenza vaccine now routine

Application of Artificial Intelligence for Pattern Recognition as a New Paradigm for Semi-automated Spontaneous Report Evaluation



Ball R, Botsis T. Can network analysis improve pattern recognition among adverse events following immunization reported to VAERS? *Clinical Pharmacology & Therapeutics* 90:271-8, 2011. doi: 10.1038/clpt.2011.119. Epub 2011 Jun 15.

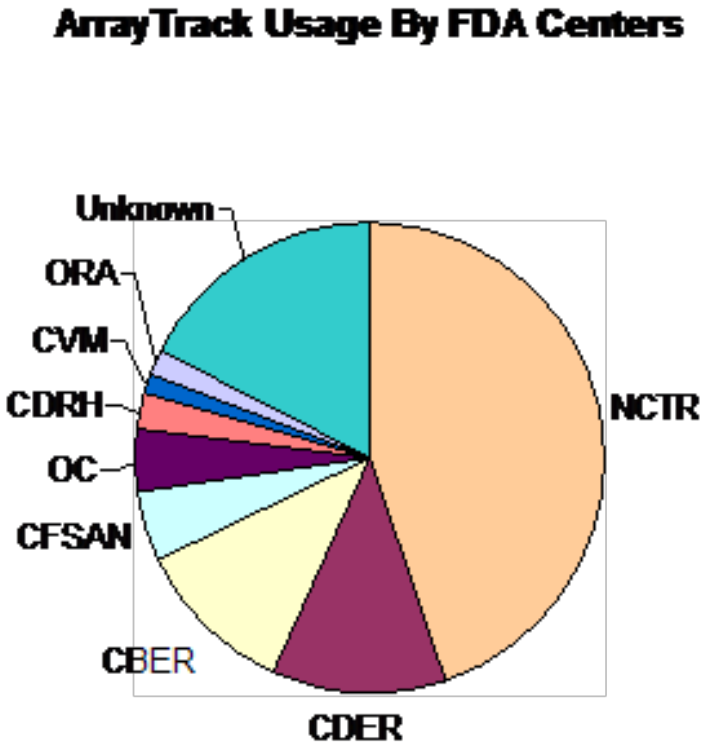
Network Analysis: Identification of a Syncope Pattern in VAERS



Text Mining for VAERS: Medical Text Classification of Anaphylaxis and Semi-automated Case Series Analysis Using Informative Feature Selection

FDA Genomic Tool: ArrayTrack

- **Developed by NCTR/FDA**
  - An integrated solution for microarray data management, analysis and interpretation
  - Support meta data analysis across various omics platforms and study data
- **FDA wide application**
  - Review tool for the FDA Voluntary eXploratory Data Submission (VXDS) program
  - >200 FDA reviewers and scientists have participated the training



Freely available to the public

- Averaged ~5000 user entries each year
- # users have been steadily grown every year; e.x., 113 new users have deposited data to ArrayTrack in the past 2 years
- ArrayTrack hosts >50,000 array data from >1600 experiments so far

MicroArray Quality Control (MAQC)

An FDA-led community wide consortium effort to assess technical performance and practical utility of emerging molecular biomarker technologies for clinical application and safety evaluation

Projects	Scientists (organizations)	Focused on	Outcomes
MAQC-I	137 (51)	Reliability of microarray technology	nature biotechnology 6 papers, 2006
MAQC-II	202 (97)	Microarray-based genomic biomarkers and GWAS	The Pharmacogenomics Journal nature biotechnology 13 papers, 2010
MAQC-III	---	Next generation sequencing	On-going

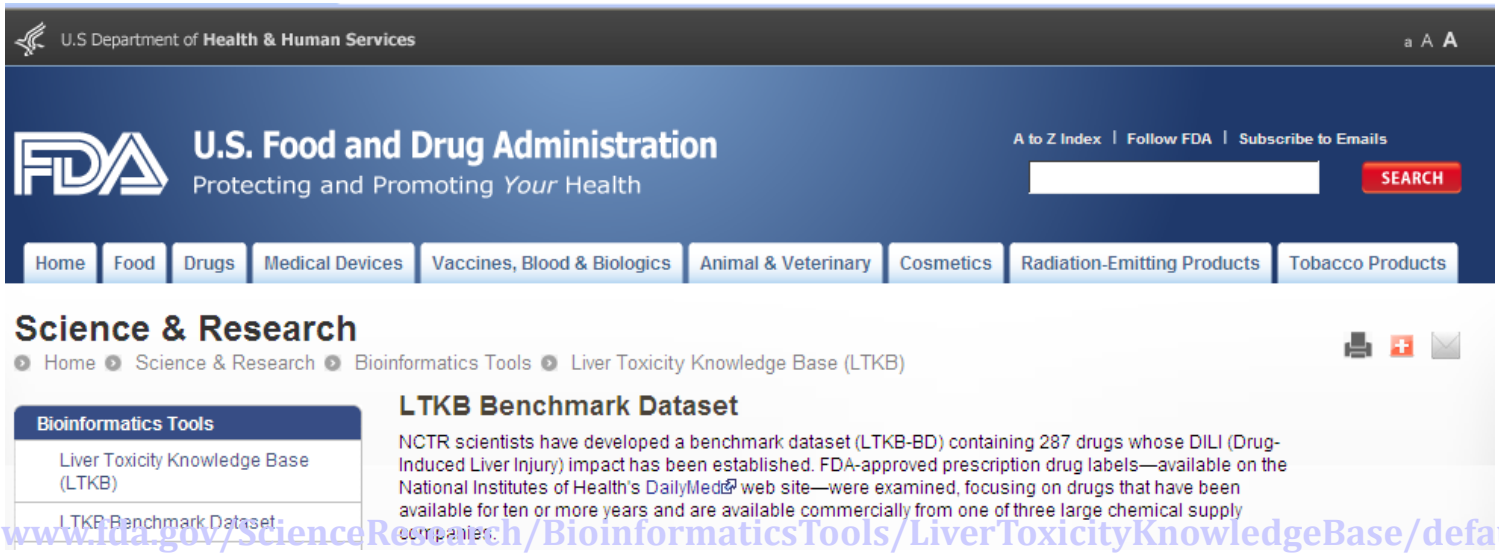
Liver Toxicity Knowledge Base

Study of drug induced liver injury (**DILI)** with emphasis on **marketed drugs**

The Liver Toxicity Knowledge Base is a public resource, containing

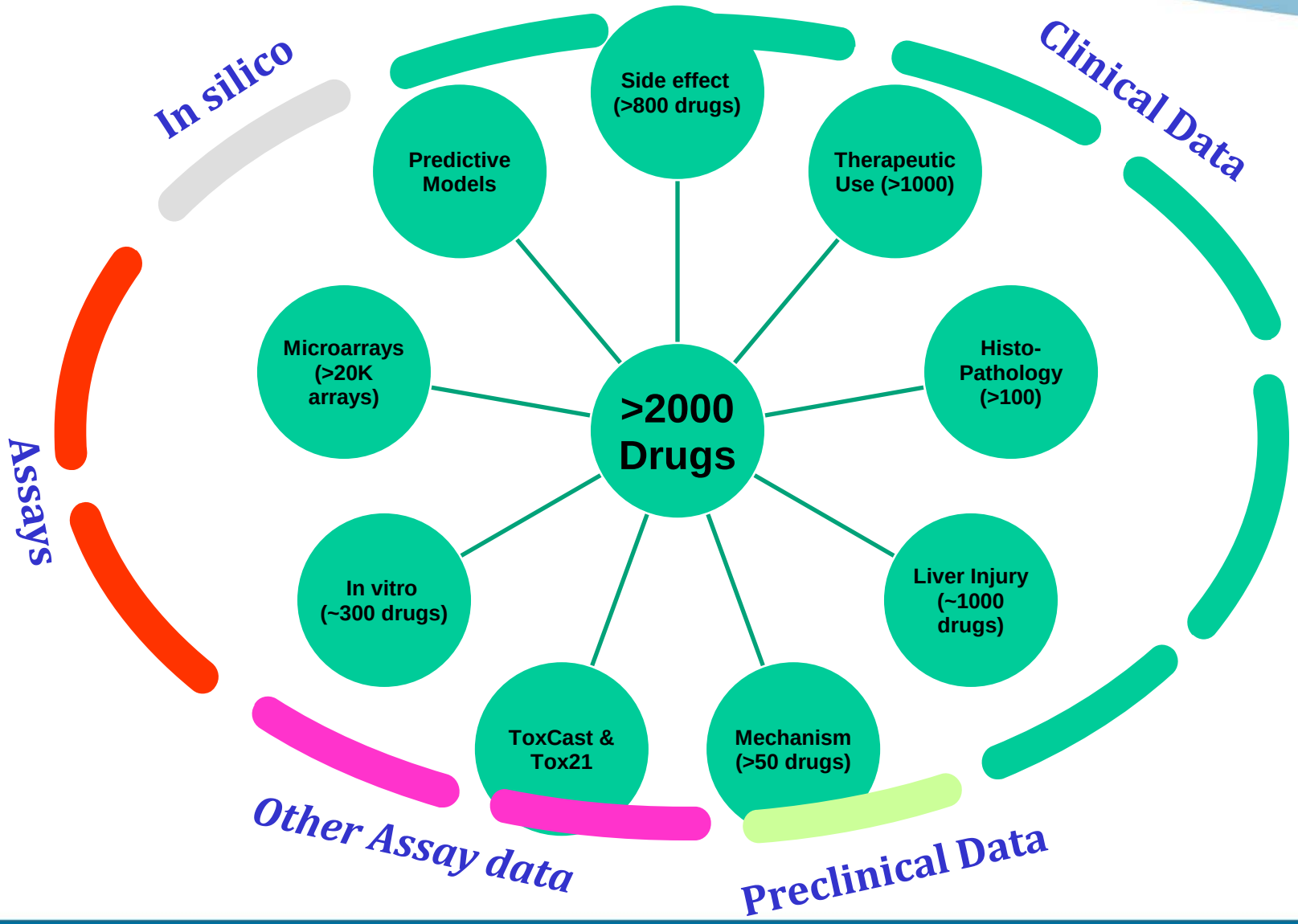
- A broad range of data associated with marketed drugs
- An array of predictive models that can be used individually or in combination for DILI assessment

Be useful for the FDA to utilize and reference when liver toxicity issues arise during the various stages of the regulatory review process.



http://www.fda.gov/ScienceResearch/BioinformaticsTools/LiverToxicityKnowledgeBase/default.htm

LTKB Data


In silico
Clinical Data
Assays
Other Assay data
Preclinical Data
Predictive Models
Side effect (>800 drugs)
Therapeutic Use (>1000)
Microarrays (>20K arrays)
>2000 Drugs
Histo-Pathology (>100)
In vitro (~300 drugs)
Liver Injury (~1000 drugs)
ToxCast & Tox21
Mechanism (>50 drugs)